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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,273	02/19/2002	Peter S. Lu	020054-002310US	6968

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EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,273

Applicant(s)

LU ET AL

Examiner

DiBrino Marianne

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a method for screening a compound to determine whether the compound inhibits immune cell signaling, said method comprising identifying a compound that inhibits the interaction between a PDZ protein and a PDZ ligand protein, classified in Class 435, subclass 7.1.

Note Absent evidence to the contrary, each of the recited PDZ proteins and PDZ ligand proteins thereof is distinct since each ligands(s) to which each of the said proteins or ligand proteins is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 1-5 encompass hundreds of GROUPS, not species.

Applicant is required to elect ONE PDZ protein and ONE PDZ ligand protein.

II. Claims 1-5, drawn to a method for screening a compound to determine whether the compound enhances immune cell signaling, said method comprising identifying a compound that enhances the interaction between a PDZ protein and a PDZ ligand protein, classified in Class 435, subclass 7.1.

Note Absent evidence to the contrary, each of the recited PDZ proteins and PDZ ligand proteins thereof is distinct since each ligands(s) to which each of the said proteins or ligand proteins is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 1-5 encompass hundreds of GROUPS, not species.

Applicant is required to elect ONE PDZ protein and ONE PDZ ligand protein.

III. Claims 6-20 and 29-32, drawn to a method of modulating immune cell signaling, said method comprising modulating an interaction between a PDZ protein and a PDZ ligand protein using a modulator that inhibits the interaction between the PDZ protein and the PL protein, including to treat an immune disorder, classified in Class 435, subclass 7.2, and Class 424, subclass 185.1.

Note Absent evidence to the contrary, each of the recited PDZ proteins and PDZ ligand proteins thereof is distinct since each ligands(s) to which each of the said proteins or ligand proteins is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 6-20 and 29-32 encompass hundreds of GROUPS, not species.

Applicant is required to elect ONE PDZ protein and ONE PDZ ligand protein.

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IV. Claims 6-20 and 29-32, drawn to a method of modulating immune cell signaling, said method comprising modulating an interaction between a PDZ protein and a PDZ ligand protein using a modulator that enhances the interaction between the PDZ protein and the PL protein, including to treat an immune disorder, classified in Class 435, subclass 7.24, and Class 424, subclass 185.1.

Note Absent evidence to the contrary, each of the recited PDZ proteins and PDZ ligand proteins thereof is distinct since each ligands(s) to which each of the said proteins or ligand proteins is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 6-20 and 29-32 encompass hundreds of GROUPS, not species.

Applicant is required to elect ONE PDZ protein and ONE PDZ ligand protein.

V. Claims 21-28 and 33-36, drawn to a modulator of binding of a PDZ protein and a PDZ ligand protein and pharmaceutical composition thereof wherein the modulator inhibits binding of a PDZ domain polypeptide and a PL domain polypeptide, and a method of making a medicament for treatment of an immune disease using a modulator that inhibits the binding of a PDZ protein and a PDZ ligand protein, classified in Class 530, subclass 324, Class 424, subclass 192.1 and Class 514, subclass 2, respectively.

Note Absent evidence to the contrary, modulators that inhibit each of the recited PDZ proteins and PDZ ligand proteins thereof is distinct since each ligands(s) to which each of the said proteins or ligand proteins is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 21-28 and 33-36 encompass hundreds of GROUPS, not species.

Applicant is required to elect modulators that inhibit binding of ONE PDZ protein and ONE PDZ ligand protein.

(It is noted by the Examiner that the limitation "The method of claim 21" recited in instant claims 27 and 28 lack antecedent basis in base claim 21 that is drawn to a modulator.)

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VI. Claims 21-28 and 33-36, drawn to a modulator of binding of a PDZ protein and a PDZ ligand protein and pharmaceutical composition thereof wherein the modulator enhances binding of a PDZ domain polypeptide and a PL domain polypeptide, and a method of making a medicament for treatment of an immune disease using a modulator that enhances the binding of a PDZ protein and a PDZ ligand protein, classified in Class 530, subclass 326, Class 424, subclass 192.1 and Class 514, subclass 2, respectively.

Note Absent evidence to the contrary, modulators that enhance each of the recited PDZ proteins and PDZ ligand proteins thereof is distinct since each ligand(s) to which each of the said proteins or ligand proteins is specific for is not obvious over the other set of ligand(s). Therefore the instant claims 21-28 and 33-36 encompass hundreds of GROUPS, not species.

Applicant is required to elect modulators that enhance binding of ONE PDZ protein and ONE PDZ ligand protein.

(It is noted by the Examiner that the limitation "The method of claim 21" recited in instant claims 27 and 28 lack antecedent basis in base claim 21 that is drawn to a modulator.)

2. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

3. The hundreds of GROUPS encompassed by Invention V and the hundreds of GROUPS encompassed by Invention VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are modulators that inhibit the binding of a PDZ domain polypeptide and a PL domain polypeptide (Invention V) or modulators that enhance the binding of a PDZ domain polypeptide and a PL domain polypeptide (Invention VI), and as such, having different and opposing effects, are not disclosed as capable of use together.

4. The hundreds of GROUPS encompassed by Inventions I, II, III and IV are different methods.

These inventions require different ingredients and process steps to accomplish the use of screening for an inhibitor (Invention I) or an enhancer (Invention II) of the interaction between a PDZ protein and a PDZ ligand protein, or of inhibiting the interaction between the PDZ protein and a PDZ ligand protein (Invention III) or enhancing the interaction between the PDZ protein and a PDZ ligand protein (Invention IV) for the purpose of modulating immune cell signaling, including to treat an immune disorder. For example, the readout on Invention I is inhibition, whereas the readout on Invention II is enhancement, whereas the modulator of Invention III is an inhibitor, whereas the modulator of Invention IV is an enhancer.

5. The hundreds of GROUPS encompassed by Inventions V and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as detection assays.

6. The hundreds of GROUPS encompassed by Inventions VI and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as detection assays.

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7. The hundreds of GROUPS encompassed by Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P., 806.05(f)).

In the instant case, the product as claimed can be made by computer modeling or non-conservative substitution of critical binding residues of known PDZ protein domains or ligands.

8. The hundreds of GROUPS encompassed by Inventions II and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P., 806.05(f)).

In the instant case, the product as claimed can be made by computer modeling or conservative substitution of critical binding residues of known PDZ protein domains or ligands.

Therefore they are patentably distinct.

9. Because these inventions are distinct for the reasons given above and the search required for any group from the hundreds of Groups encompassed by Inventions I-VI is not required for any other of the hundreds of Groups encompassed by Inventions I-VI and the hundreds of Groups encompassed by Inventions I-VI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

10. **If Applicant elects one of the hundreds of GROUPS encompassed by Inventions I or II**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method of screening a compound and specific method steps (**a specific portion of the PDZ domain protein and a specific partial sequence of the PL protein**, for example, the entire SHANK1 protein and PAG and the method steps recited in instant claim 2) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

11. **If Applicant elects one of the hundreds of GROUPS encompassed by Inventions III or IV**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method and a specific condition to be treated (**a specific modulator of a specific PDZ protein/PL ligand combination**, for example, a polypeptide that comprises amino acid residues 2 to 100 of the C-terminus of SHANK1 protein and treating the autoimmune disease RA wherein the PL protein is PAG) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

12. **If Applicant elects one of the hundreds of GROUPS encompassed by Inventions V or VI**, Applicant is further required to (1) elect a single disclosed species (**a specific modulator of a specific PDZ protein/PL ligand combination**, for example, a polypeptide that comprises amino acid residues 2 to 100 of the C-terminus of SHANK1 protein and treating the autoimmune disease RA wherein the PL protein is PAG) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

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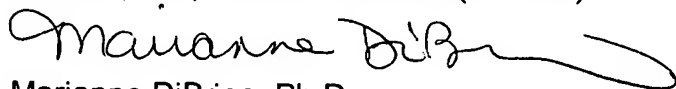
17. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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